

Title: SAFETY PRESSURE DEVICE FOR BODY FLUID EXTRACTION  
Application Number: 10/706,322  
Filing Date: 11/12/2003  
Inventor: Enrique Carlos Leira  
Attorney Docket No: SLU 00-013 US  
Examiner: Phillip A. Gray  
Art Unit: 3767

## Remarks:

[006] Applicant is not disclaiming any subject matter. The changes are proposed to expedite the examination process. Applicant reserves all rights to the invention as specified and claimed in the original application. The Amendment adds no new subject matter.

### Remarks Regarding the Amendment to the Claims

[007] Please amend Claim 1 by making the following insertions and deletions. Insert “the valve can be in only one of two positions (i) a first position occurring” after the phrase, “such that” and before the phrase, “when a pressure differential...” Insert “completely” after the phrase, “the rod is displaced to” and before the phrase, “obstruct the fluid...” Insert “a second position occurring” after the phrase, “to the outlet and (ii)” and before the phrase, “when the pressure differential...” Replace the phrase, “to allow” with “, allowing” after the phrase, “the rod is not displaced” and before the phrase, “the fluid to flow...” Insert “unrestricted” after the phrase, “the fluid to flow” and before the phrase, “from the inlet to the outlet.”

[008] Please amend Claim 17 by making the following insertions and deletions. Insert “the valve can be in only one of two positions (i) a first position occurring” after the phrase, “such that” and before the phrase, “when a pressure differential...” Insert “completely” after the phrase, “the rod is displaced to” and before the phrase, “obstruct the body fluid...” Insert “a second position occurring” after the phrase, “to the outlet, and (ii)” and before the phrase, “when the pressure differential...” Replace the phrase, “to allow” with “, allowing” after the phrase, “the rod is not displaced” and before the phrase, “the body fluid to flow...” Insert “unrestricted”

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after the phrase, “the body fluid to flow” and before the phrase, “from the inlet to the outlet;”.

Insert “and” after the phrase, “from the inlet to the outlet;” and before the phrase, “b. inserting the needle into a body...” Insert “unrestricted” after the phrase, “the body fluid flows” and before the phrase, “to the outlet of the housing...” Insert “completely” after the phrase, “the rod is” and before the phrase, “displaced and body fluid is not allowed...”

[009] Please amend Claim 28 by making the following insertions and deletions. Insert “the valve can be in only one of two positions (i) a first position occurring” after the phrase, “such that” and before the phrase, “when a pressure differential...” Insert “a second position occurring” after the phrase, “from the inlet to the outlet; and (ii)” and before the phrase, “when the pressure differential...” Insert “unrestricted” after the phrase, “which thereby allows” and before the phrase, “flow of the body fluid...” Insert “and” after the phrase, “from the inlet to the outlet;” and before the phrase, “b. ~~and~~ the ancillary device is selected...” Delete “~~and~~” after the phrase, “the ancillary device is selected...” and after the “b.”

[010] Support for these insertions and deletions can be found in Paragraph [0012] of the Specification. It states, “[t]he rod *either* allows the fluid to flow through the channel *or* blocks flow through the fluid channel at a preset pressure.” (Emphasis added). The Specification clearly describes a valve with only two possible positions, open and closed. In a first position, the valve is open and the fluid flows unimpeded or unrestricted. In a second position, the valve is closed and the flow is blocked completely.

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[011] Additional support for this amendment can be found throughout the Specification.

Paragraph [0009] describes the valve, “a pressure sensitive valve that *shuts off* the flow of body fluid...” Paragraph [0013] describes the valve, “...while the pressure is below a preset value...allows the body fluid to *flow unimpeded* through the rod via the rod channels...[w]hen the body fluid pressure is at or above a preset value...[the rod] *closes off* the outlet, thereby *blocking* the flow of the fluid...” Paragraph [0014] describes the valve, “...while the pressure is below a preset value and allows the fluid to flow *unimpeded*...[w]hen the pressure of the fluid pressure [*sic*] is at or above a preset value...the channel is *closed off*, thereby *blocking* the fluid flow...” Paragraph [0017] describes the valve, “This *shutting off* of body fluid flow at a preset value ensures greater patient safety...” Paragraph [0019] describes the valve, “When the pressure at the tip of the needle is preferably below 200 mm of H<sub>2</sub>O, *the flow* of CSF...is *unrestricted*...When the pressure is preferably at or above 200 mm of H<sub>2</sub>O, *the flow* of body fluid...is *cutoff*...” Paragraph [0060] states, “The term ‘pressure sensitive valve’ means a device that is set to *open or close* based on a preset pressure value.” Paragraph [0062] describes the valve, “...which *shuts off the flow* of fluid whenever the fluid pressure is at or greater than a preset value. [T]he pressure sensitive valve in the *open position* is shown in Figs. 1 and 2, with the pressure sensitive valve in the *closed position* shown in Figs. 1A and 2A.” Many other examples can be found throughout the Specification. (Emphasis added throughout).

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**Claim Rejections – 35 U.S.C. § 102**

[012] The § 102 novelty rejections of claims 1-7, 13, 16-22, 24, and 27 are improper. The Applicant respectfully requests that the Examiner reconsider and withdraw them. The Examiner asserts that “TEH [U.S. Patent Number 5,514,110] discloses an automatic flow control device, method, and kit, which is used for collecting a fluid comprising a pressure sensitive valve.” (Page 2, Office Action). However, TEH fails to describe, expressly or inherently, each and every element as set forth in the Applicant’s claims.

[013] Section 2131 of the Manual of Patent Examining Procedure (“MPEP”) states:

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” (Citations omitted).

[014] TEH fails to describe, expressly or inherently, each and every element as set forth in the Applicant’s claims. One element of the Applicant’s pressure sensitive valve is that it can be in one of only two possible positions – open or closed. The Specification repeatedly refers to these two possible positions. (see Paragraphs [0013], [0014], [0023], [0024], [0060], [0062], [0074], and [0082]). TEH describes a pressure sensitive valve that has more than only two possible positions. TEH describes, “The upstream opening is disposed adjacent the fluid restrictor to *variably restrict* the volume of fluid passing to the interior of the pin.” (Column 2; Lines 16-18; emphasis added). TEH may have an infinite number of positions to control fluid flow. TEH also fails to disclose a possible valve position where fluid flow is shut off (or completely restricted). Moreover, TEH fails to describe every element of the Applicant’s method claims (Claims 17-27).

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[015] The Applicant's proposed Amendment to the Claims clarifies the Applicant's claimed subject matter. The Amendment to the Claims clarifies that one element of the Applicant's pressure sensitive valve is that it has only two possible positions – open and closed. This element (the Applicant's valve having only two possible positions – open and closed) is not found in the prior art. Each of the Applicant's other claims (Claims 2-16; 18-27; and 29-38) are dependent from, and include all of the elements of, one of the three amended claims (Amended Claim 1, Amended Claim 17, or Amended Claim 28). The Amendment to the Claims clarifies that all of the Applicant's Claims include an element that is not found in the prior art. Therefore, the § 102 novelty rejections of claims 1-7, 13, 16-22, 24, and 27 are improper and the Applicant respectfully requests that the Examiner reconsider and withdraw them.

#### **Claim Rejections – 35 U.S.C. § 103**

[016] The Examiner's presumption, "that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made," is correct. All joint inventors were under an obligation to assign their respective inventions to a common entity, namely, Saint Louis University.

[017] The § 103 obviousness rejections of claims 8-11, 12, and 23 are improper. The Applicant respectfully requests that the Examiner reconsider and withdraw them. Concerning claims 8-11, the Examiner asserts that "TEH discloses the claimed invention except for the preset value is at or greater than 10 mm of H<sub>2</sub>O, 50 mm of H<sub>2</sub>O, 100 mm of H<sub>2</sub>O, or between 179 mm and 221

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mm of H<sub>2</sub>O.” Concerning claims 12 and 23, the Examiner asserts that “TEH discloses the claimed invention except for the fluid comprising body fluid, blood, or CSF.”

[018] The Applicant respectfully requests that the Examiner reconsider and withdraw the § 103 obviousness rejections of claims 8-11, 12, and 23 in light of the Applicant’s Amendment to the Claims. The Specification refers to evidence of a “Secondary Consideration” (long-felt, unresolved need for a device of this nature). Moreover, a *prima facie* case of obviousness has not been established. First, TEH addresses a different problem than the Applicant. Second, TEH fails to teach or suggest every claim limitation.

[019] Section 2141(I.) of the MPEP states:

“Patent examiners carry the responsibility of making sure that the standard of patentability enunciated by the Supreme Court and by the Congress is applied in each and every case. The Supreme Court in *Graham v. John Deere*, 383 U.S. 1, 148 USPQ 459 (1966), stated:

Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented. As indicia of obviousness or nonobviousness, these inquiries may have relevancy...”

[020] The Examiner is invited to consider evidence of a “Secondary Consideration” that can be found in the Specification. The Specification points out a long-felt, but unresolved need for the present invention in paragraph [0071] where it states,

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"While several alternative devices to measure CSF pressure have been proposed [cite to Patent Nos. 3,610,228; 4,790,193; 4,817,629; and 5,935,083], they were too complex and therefore never gained clinical acceptance. Therefore, there is a need for a simple and feasible automatic safety pressure valve that could be attached to the LP needle opening."

[021] Moreover, in light of the Applicant's Amendment to the Claims, a *prima facie* case of case of obviousness has not been established. Section 2142 of the MPEP states:

"To reach a proper determination under 35 U.S.C. 103, the examiner must step backward in time and into the shoes worn by the hypothetical "person of ordinary skill in the art" when the invention was unknown and just before it was made. In view of all factual information, the examiner must then make a determination whether the claimed invention "as a whole" would have been obvious at that time to that person. Knowledge of applicant's disclosure must be put aside in reaching this determination, yet kept in mind in order to determine the "differences," conduct the search and evaluate the "subject matter as a whole" of the invention. The tendency to resort to "hindsight" based upon applicant's disclosure is often difficult to avoid due to the very nature of the examination process. However, impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art.

#### ESTABLISHING A *PRIMA FACIE* CASE OF OBVIOUSNESS

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure."  
[Citations Omitted]

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A *prima facie* case of obviousness has not been established because TEH addresses a different problem than the Applicant and fails to teach or suggest every claim limitation.

[022] TEH addresses a different problem than the Applicant. Section 2143.01 VI of the MPEP states:

“If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959) (Claims were directed to an oil seal comprising a bore engaging portion with outwardly biased resilient spring fingers inserted in a resilient sealing member. The primary reference relied upon in a rejection based on a combination of references disclosed an oil seal wherein the bore engaging portion was reinforced by a cylindrical sheet metal casing. Patentee taught the device required rigidity for operation, whereas the claimed invention required resiliency. The court reversed the rejection holding the “suggested combination of references would require a substantial reconstruction and redesign of the elements shown in [the primary reference] as well as a change in the basic principle under which the [primary reference] construction was designed to operate.” 270 F.2d at 813, 123 USPQ at 352.)”

Here, the Examiner’s proposed modification of TEH would change its principle operation. TEH “provide[s] an inexpensive, easy-to-operate IV fluid flow control device which can *accurately control* the flow of fluid *into* a patient.” (Column 2, Lines 6-9, emphasis added). The purpose of TEH is to regulate fluids flowing into a patient. The purpose of the Applicant’s device is to allow fluid to flow *out* of a patient, regardless of flow rate, so long as the fluid pressure is below a certain, safe, threshold level. At or above that certain, safe, threshold level, the Applicant’s device *completely blocks* all fluid flow *out* of the patient. The purpose of the Applicant’s device



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is significantly different than the purpose of TEH. Therefore, TEH is an inappropriate piece of art to use for a § 103 obviousness rejection.

[023] Moreover, TEH fails to teach or suggest every claim limitation of the instant invention.

Section 2143.03 of the MPEP states:

“To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). “All words in a claim must be considered in judging the patentability of that claim against the prior art.” *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). ***If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. In re Fine***, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).” (Emphasis added).

Here, independent claims 1, 17, and 28, as amended, are not obvious because they contain an additional element that is not found in the prior art. The element not found in the prior art is the Applicant’s pressure sensitive valve with only two possible positions – open and closed. Claims 8-11 and 12 depend from independent claim 1 and claim 23 depends from independent claim 17. Therefore, because the prior art fails to teach or suggest every claim limitation, as amended, the § 103 obviousness rejection is improper and the Applicant respectfully requests that the Examiner reconsider and withdraw it.

[024] The § 103 obviousness rejections of claims 14, 15, 25, 26, and 28-38 are improper. The Applicant respectfully requests that the Examiner reconsider and withdraw them. The Examiner asserts that these claims are “unpatentable over TEH in view of Bierman (U.S. Patent Number 2,535,998).” However, TEH in view of Bierman still fails to teach or suggest every claim limitation of the Applicant’s claims, as amended. In light of the Applicant’s Amendment to the

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Claims, the Examiner is respectfully invited to reconsider and withdraw the § 103 obviousness rejections of claims 14, 15, 25, 26, and 28-38.

### **Conclusion:**

[025]

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicant therefore respectfully requests that the Examiner reconsider all presently outstanding rejections and that they be withdrawn. It is believed that a full and complete response has been made to the outstanding Office Action, and as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, he is invited to telephone the undersigned at the number provided.

### **Correspondence Address: Customer Number 33436**

Respectfully submitted,

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